TABLED BY HEALTH DEPARTMENT
28/10/13

Response to Indicative Questions

for the

Standing Committee on Uniform Legislation and Statutes Review Inquiry into the Medicines, Poisons and Therapeutic Goods Bill 2013

Departmental Officers:

Neil Keen	***Chief Pharmacist***
Jane Carpenter	***Manager, Legislation & Licensing***
Robyn Daniels	***Senior Solicitor***

Standing Committee on Uniform Legislation and Statutes Review Inquiry into the Medicines, Poisons and Therapeutic Goods Bill 2013

1. Outline of the Bill

The short title of the Bill states it is an Act —

"• to regulate and control the manufacture and supply of medicines, poisons and therapeutic goods; and

• to repeal the *Poisons Act* 1964, the *White Phosphorus Matches Prohibition Act* 1912 and various regulations; and

• to amend the *Health Act* 1911, *Misuse of Drugs Act* 1981 and various other written laws and, for incidental and related purposes."

The Bill updates the present *Poisons Act* 1964 which regulates and controls the supply of medicines and poisons. It does this by:

- creating offences for the manufacture, supply, prescribing, use and possession of medicines and poisons without the proper authority;
- authorising particular groups of professionals;
- licensing particular groups of persons;
- regulating a natural person who manufactures and supplies therapeutic goods;
- creating a regime to regulate, monitor and record the use and potential misuse of drugs of addiction; and
- creating a regime for the investigation and enforcement of these controls.

2. Please describe Part 6 of the Bill

This part ensures that natural persons manufacturing and or trading therapeutic goods exclusively within this jurisdiction are subject to the same regulatory framework as corporations – ie conforming to the regulatory regime that allow the inclusion of their products on the Australian Register of Therapeutic Goods (ARTG). Only therapeutic goods deemed to be safe, efficacious and of high quality can be included on the ARTG.

This is achieved by adopting the powers of the Commonwealth *Therapeutic Goods Act* 1989 (Clth TGA) and its subsidiary *Therapeutic Goods Regulations* 1990. The Clth TGA provides for the:

- regulation of products based on an assessment of risks against benefits;
- maintenance and enforcement of standards for the labeling and packaging of therapeutic goods;
- regulation of the advertising of therapeutic goods to both health practitioners and consumers;
- coordination of a national recall and alert system;
- maintenance of a publically accessible register of therapeutic goods approved for supply across Australia (the ARTG); and
- other functions relating to human tissue products, unapproved therapeutic goods and the export of therapeutic goods.

The Clth TGA presently regulates therapeutic goods produced by corporations for the quality of their manufacturing (including the quality of raw materials); the consistency of the product; the fitness of the product for purpose (Does the product provide the benefit it claims?); product safety (including the potential for poisoning) and adverse reactions during normal use of the therapeutic good.

3. **(a) What is the name of the Intergovernmental Agreement that formalises the State of Western Australia adopting the Clth TGA as part of WA law.**
   (b) Please describe the process by which the legislative clauses of the Bill were formally agreed to between the State of Western Australia and the Commonwealth
   (c) When did this occur?

Department of Health officers sought from the Department of Premier and Cabinet copies the Council of Australian Governments (COAG) records for 2005. They were unable to provide a copy of an Intergovernmental Agreement, but where able to furnish a copy of a letter signed by the Acting Prime Minister (21 July 2005) referencing an "Out of Session" agreement to the decision. (Attachment 1)

Department of Health records indicate:

- the *Final Report of the National Competition Policy Review of Drugs Poisons and Controlled Substances Legislation* (the Galbally Review) was presented to the Australian Health Ministers' Conference (AHMC) in January 2001. Recommendation 23 of the Galbally Review was that: *all Commonwealth, State and Territory jurisdictions agree that all States and Territories adopt the Therapeutic Goods Act 1989 by reference into the relevant legislation. (*Attachment 2)
- A response to the Galbally Review recommendations was prepared by a Working Party of the Australian Health Ministers' Advisory Council (AHMAC) in April 2003. The Working Party recommended acceptance of Recommendation 23 of the Galbally Review; (Attachment 3)
- All recommendations of the AHMAC Working Party were unanimously accepted by the COAG on 28 June 2005.
- The Minister for Health approved (31 October 2010) incorporation into the Bill the adoption by reference of the Commonwealth *Therapeutic Goods Act* 1989 for the regulation of sole traders who manufacture and supply these therapeutic goods exclusively within Western Australia.

4. **What other Acts and Regulations interact with this Bill?**

The primary Acts that interact with this Bill are the *Misuse of Drugs Act* 1981, the *Health Practitioner Regulation National Law (WA) Act* 2010 and the *Health Professionals (Special Events Exemption) Act* 2000.

There is no interaction between Part 6 of the Bill and any other Acts or regulations.

The *Misuse of Drugs Act* 1981 interacts with the Bill to the extent that Schedule 8 and 9 substances (and Schedule 4 Reportable medicines) form the basis of the substances that if misused are included in the Schedules for prosecution under the Misuse of Drugs Act.

The *Health Practitioner Regulation National Law (WA) Act* 2010 interacts with the Bill to the extent it authorises the handling of medicines by health practitioners.

The *Health Professionals (Special Events Exemption) Act* 2000 interacts with the Bill to the extent that it authorises overseas health professionals attending international sporting events in this state, to conduct their professional practice on their own participants.

The Bill interacts with a number of other Acts, which are included as consequential amendments to the Bill. Of note is the *Health Act* 1911 which will be amended considerably to remove sections related to therapeutic goods that predate the enactment of the Clth TGA.

Other Acts are impacted on largely through definitional changes.

5. **What is the interaction of the Commonwealth Therapeutic Goods Law with this Bill?**

The interaction of the Commonwealth Therapeutic Goods Law with this Bill will be the inclusion in WA law of the powers and authorities associated with the Clth TGA to regulate the activities of natural persons manufacturing and or trading therapeutic goods exclusively within this jurisdiction.

The objects of the Clth TGA that is relevant to Part 6 of the Bill at sec 4(1)(a) state: "(to) *provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods*....".

Sections 6AAA-AAE, 6B & 6C of the Clth TGA provide for the adoption of Commonwealth law into the law of States and Territories for the purposes outlined in Part 6. Section 7A provides for the Secretary (of the Commonwealth department) to authorise officers of a Department of State to exercise powers under the Clth TGA. (Attachment 4)

6. **What provisions are there in the Bill for the Western Australian Parliament to disallow any further amendments to the TGA (Cth) being considered for incorporation in the WA Act?**

The Bill as presently drafted allows for the modification of the application of the Clth TGA through:

Clause 78(4) (in association with Clause 148) provides for the modification of the text of the Clth Therapeutic Goods Law within Part 6.

Clause 82(2) on the application of Commonwealth administrative law includes the provision of exemption by regulation.

Clause 93 on the relationship with other State laws provides for regulation to override, modify or delete specified enactment, or provisions of the *Therapeutic Goods Law (WA)*. In addition sub-clause 93(3) (in association with sub clause 93(2)) provides for relief from the imposition of the Clth TGA should the State wish to retrospectively modify amend or delete certain provisions with the Therapeutic Goods Law (WA) from impacting upon natural persons manufacturing and or trading therapeutic goods exclusively within this jurisdiction.

Clause 148 is a general regulation making power.

Clause 163 allows the Minister to exempt certain therapeutic goods from the requirements of the Therapeutic Goods Law (WA).

7. What are the functions and powers of the Commonwealth Minister in relation to clause 86?

This provision identifies the Commonwealth Minister as having the same functions and powers under the *Therapeutic Goods Law (WA)* as the Clth TGA and its regulations, codes and manufacturing principles to the extent that Clause 78(3) allows; that is the regulation of natural persons manufacturing and or trading therapeutic goods exclusively within this jurisdiction.

8. What are the functions and powers of the WA Minister for Health in relation to Part 6?

The WA Minister for Health has no direct functions in relation to Part 6.

The WA Minister for Health has regulation making powers that will impact on Part 6. As stated in question 6 above, these include:

Clause 78(4) (in association with Clause 148) - modification of the text of the Clth Therapeutic Goods Law for the purposes of Part 6.

Clause 82(2) - provision to exempt by regulation the application of Commonwealth administrative law.

Clause 93 - regulation to override, modify or delete specified enactment, or provisions (including retrospectively) of the *Therapeutic Goods Law (WA)*.

Clause 148 - a general regulation making power.

At *Clause 163* the Minister has a specific power to exempt certain therapeutic goods from requirements of the Therapeutic Goods Law (WA).

9. What are the functions and powers of the Commonwealth Secretary in relation to Part 6?

This provision identifies the Commonwealth Secretary as having the same functions and powers under the *Therapeutic Goods Law (WA)* as in the Clth TGA and its regulations, codes and manufacturing principles to the extent that Clause 78(3) allows; that is the regulation of natural persons manufacturing and or trading therapeutic goods exclusively within this jurisdiction.

10. What are the functions and powers of other persons under clause 88?

The functions of the authorised persons under Clause 88 are to investigate the activities of natural persons manufacturing and or trading therapeutic goods exclusively within this jurisdiction.

Section 7A of the Clth TGA provides for the Secretary (of the Commonwealth department) to authorise officers of a Department of State to be "*authorised persons*" under the Clth TGA.

Section 48 of the Clth TGA sets out the powers of authorised person. (Attachment 4)

11. Does the Bill confer powers on the Commonwealth?

The Bill confers power to the extent (at Clause 78(3)) it adopts the Clth TGA to apply to "things done or omitted to be done by persons who are not corporations and things done or omitted to be done in the course of trade or commerce within the limits of Western Australia" – that is natural persons manufacturing and or trading therapeutic goods exclusively within this jurisdiction.

12. Are any amendments to other Acts being considered if the amendments to this Bill are passed?

No –the inclusion of Part 6 into the Bill will only impact on natural persons manufacturing and or trading therapeutic goods exclusively within this jurisdiction.

13. What would be the effect of Parliament not passing Part 6 of the Bill?

Currently there is no regulation on the quality, safety and efficacy of therapeutic products made and supplied by natural persons operating exclusively within this state. Natural persons or sole traders who manufacture and or trade therapeutic goods within the State will be without regulatory checks.

The State will continue to have no power to remove unsafe or dangerous goods, or force the withdrawal of false claims for cures.

Western Australia will not have implemented an "Out of Session" COAG recommendation.

14. Please clarify clause 93 in relation to possible retrospective effect of regulations?

As articulated above, this clause provides for the State to make regulations that may counter or modify the impact or application of the *Therapeutic Goods Law (WA)*. In addition this clause mitigates against the impact the imposition of any amendment to the Clth TGA that is opposed by the State, which is not immediately amended by regulation under the Therapeutic Goods Law (WA).

15. Clarification on the extent of 5 year review promised at clause 152?

This clause requires a review of the operation and effectiveness of the Act. To the extent, where possible, the review would be conducted on the components of the Clth TGA that had been operationalised within Western Australia.

It does not contemplate reviewing the Clth TGA, rather its impact on regulating the practice of natural persons who seek to manufacture and produce therapeutic goods within the State.

Attachment 1

Copy of Letter from A/Prime Minister Mark Vale to Premier Geoff Gallop

Young

21903

ACTING PRIME MINISTER
CANBERRA

200509594
PREMIERS

The Hon R J Carr MP
Premier of New South Wales
GPO Box 5341
SYDNEY NSW 2001

Dear Premier

Thank you for your letter of 24 June 2005 to the Prime Minister regarding out of session COAG endorsement of the proposed response to the Galbally Review of Drugs, Poisons and Controlled Substances Legislation.

COAG has now endorsed the response, as of 28 June 2005. The National Coordinating Committee on Therapeutic Goods (NCCTG) will oversee implementation of the response and will commence a consultation process on the new arrangements shortly. That process will include industry.

You raised some concerns about recommendation 16, particularly in relation to recording of pseudoephedrine sales. The NCCTG has agreed that an appendix to a new draft scheduling standard will set out the Schedule 3 substances that all jurisdictions have agreed require mandatory recording.

States and territories will be consulted regarding the legislative arrangements for the new trans-Tasman therapeutic products agency. The draft legislation will be released for comment later in 2005.

I have provided a copy of this letter to the other Premiers and Chief Ministers and to the Minister for Health and Ageing, the Hon Tony Abbott MP.

Yours sincerely

Signed

21 JUL 2005

MARK VAILE

27 JUL 2005
Premier & Cabinet

CANBERRA

With the Compliments

of the

Acting Prime Minister

CANB. ML 549 22JUL05

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POSTAGE PAID

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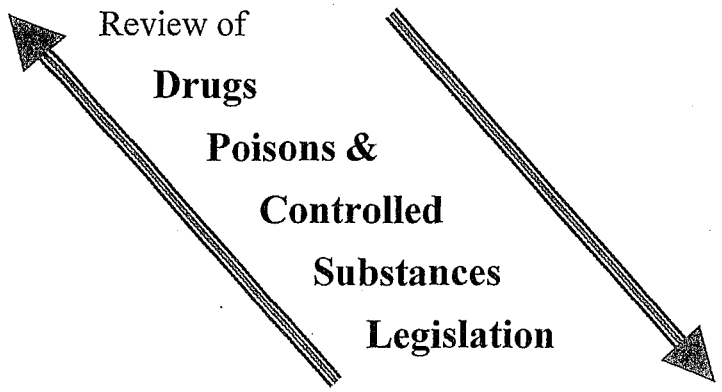
The Hon Dr G I Gallop MLA
Premier of Western Australia
197 St Georges Terrace
PERTH WA 6000

ACTING PRIME MINISTER
CANBERRA

Attachment 2



A Council of Australian Governments Review

Final Report Part A

January 2001

EXECUTIVE SUMMARY

The Review of Drugs, Poisons and Controlled Substances Legislation here presents its Final Report. Having conducted the research, consultation and analysis under Competition Principles, the Review is satisfied that most of the current controls provide a net benefit to the community as a whole in relation to the use of substances that have the potential to cause harm. The recommendations for change are in the areas of increasing national uniformity, improving efficiency, reducing the level of control where possible, and improving the net benefit to the community as a whole of those controls which rely on professional practice to be effectual.

Freedom from harm to the individual and the community as a whole is the key objective sought from the controls. The Review considered the range of harms the legislative controls were put in place to alleviate. It established that the use of certain poisonous substances, although of benefit to the community, can and do result in harm, and that this would be expected to worsen under unrestrained deregulation. Effort needs to be placed in reducing the current level of harm and the Review considered alternatives to regulation to minimise the restrictions on competition while achieving this, particularly mechanisms to improve the information available to consumers.

The harms from inappropriate use may lead to hospital, medical and social costs. The costs have an impact on government, individuals and the community as a whole. These harms include accidental and deliberate poisoning, medicinal misadventures and abuse. Because, drugs, poisons and controlled substances are widely used in the community, with most Australians using one or more every day, the Review concluded that the total potential for harm warrants acceptance of reduced competition and higher costs in some circumstances.

Used appropriately, these substances have considerable benefits for the community. For example, medicines play an important and, in some cases, a life-saving role in improving the health of humans and animals. Other substances improve the quality and quantity of food production or make household tasks, such as cleaning, easier. Maintenance of the relevant industries with the minimum regulation necessary and enhanced competition is also important.

The substances under review are included in human medicines,[1] veterinary products, garden pesticides, household cleaners and a variety of products used by farmers, horticulturists and various industries. For simplicity they can be referred to as medicines (covering human and animal) and poisons.

The controls under review

State and Territory governments have a range of medicines and poisons legislation that imposes restrictions on who can supply these substances, to whom they can be

[1] Medicines are defined to include prescription medicine, 'over-the-counter' and 'complementary' medicines.

supplied, how they can be supplied and in what circumstances. These restrictions are supported by a range of other controls.

Other legislation concerned with public health and safety in the use of substances includes the Commonwealth's *Therapeutic Goods Act 1989* and the *Agricultural and Veterinary Chemical Code Act 1994*, both of which control supply of products by a registration process. The Review was concerned with these controls in so far as they relate to, or overlap with, the State and Territory legislation. There are also links, for public health purposes, with occupational health and safety legislation concerned with substances in any form in the workplace, and food standards which restrict levels of pesticide residues, contaminants and food additives.

The other related legislation, which the Review identified as being particularly relevant to a review of medicines and poisons control, and on which the system of controls in part rely, is the State and Territory legislation regulating professional practice – in particular the medical, pharmacist and veterinarian professions.

The review process

The Review examined the legislation nominated for review and identified those provisions which impact on competition, the extent of that impact and their effect on the economy as well as a range of alternatives. The costs and benefits of the current controls and the alternatives, both legislative and non-legislative, were examined, as required by the Terms Reference. Also, as required by the Terms of Reference, the Review considered mechanisms to improve the overall efficiency of the system, including measures to minimise the compliance costs that flow from medicines and poisons legislation.

The independent Chair of the Review was Ms Rhonda Galbally, Managing Director of the Australian International Health Institute, aided by a Steering Committee comprising representatives of the Commonwealth and all States and Territories. In undertaking the Review, Ms Galbally consulted widely with a range of stakeholders in all jurisdictions. The information provided by stakeholders, both orally and in written submissions, together with research undertaken by the Review Secretariat was analysed to establish the costs and benefits of the current system, identify alternatives and assess the costs and benefits of those alternatives.

Stakeholder comments

No stakeholder proposed total deregulation and there was strong support for the objectives of the current legislation. In general, the current form and level of controls were considered effective in providing a net benefit to the community as a whole, but the benefit of some specific controls was doubted and the way in which the controls are applied was queried with respect to duplication, inefficiency and transparency. Across all submissions from all sectors, the single topic raised most often was a lack of uniformity across jurisdictions and the costs that this imposes on industry and, to a lesser extent, health professionals and government.

Clarification of objectives

The Review identified the objectives of the controls imposed by drugs, poisons and controlled substances legislation as to protect and promote public health by measures targeted at preventing poisoning, medicinal misadventure, and abuse of drugs. Most of the controls directly address the information asymmetry for consumers as purchasers of medicines and poisons, so that restrictions on access, requiring professional intervention and insisting that certain information be available are intended to improve the safe and efficacious use of potentially hazardous products.

Nature of the restrictions on competition

There are two broad classes of restriction on competition in medicines and poisons legislation: restrictions on WHO can supply, and restrictions on HOW these substances can be supplied. Licensing controls the entry of an operator into a business handling medicines or poisons, preventing or removing problem traders from the market. In conjunction with licensing, the *Schedules* provide the basis for the major legislative restrictions that control the manner in which medicines and poisons must be supplied. The restrictions attached to schedules in the respective State and Territory relevant Acts and Regulations specify who may sell, or supply, who may have access, and the amount and form of goods supplied. These controls are complemented by further specific controls that apply to matters such as advertising, supply of medical samples, labelling, packaging, storage, recording, reporting and disposal of unwanted medicines.

Effect of the restrictions on competition

The controls clearly restrict competition, particularly those which restrict market entry. By reducing competition from others, these restrictions may add to costs for industry, which are then passed to consumers through higher product prices.

Analysis of benefits and costs

It is not always possible to relate benefits to a particular control and in some cases it may well be a combination of factors, including several control measures that contribute to that benefit and impose the costs. The benefits of restricting access include lower hospital, medical and social costs through a reduction in accidental poisoning, deliberate poisoning, diversion to the illicit drug market and medicinal misadventure.

Consumers benefit from increased efficacy of medication with reduced medical costs and loss of income, as well as reduced pain and suffering. Farmers and pet owners experience similar benefits in caring for animals. Everyone benefits from more safe and effective use of chemicals in weed or insect control in an improved productivity and lifestyle. Governments benefit from reduced hospital and medical expenditure and cost-effective use of medical and pharmaceutical subsidies.

There are costs for industry, consumers, traders and government in maintaining restrictions on market entry and how medicines and poisons may be supplied.

However, a cost to one sector is sometimes a benefit to another. The Review considered a range of alternatives for each control.

With reduced competition in the industry, the sector's potential size and dynamism is likely to be reduced. This is predicted on the fact that general competition keeps costs and prices down and encourages innovation in service quality and products. Hence, under the current restrictions, the sector's contribution to the national economy may be smaller than otherwise. However, this cannot be confirmed because of the lack of good evidence of the effects of industry regulation on economic activity. Nonetheless the Review was able to reach some general conclusions on the effects of the controls on competition and the economy.

Generally, the Review considered that the level of regulation proposed under scheduling be in keeping with the hazards from inappropriate use, and the cost of the regulation is judged as being justified by the benefits from it.

Consider alternatives and make recommendations

The Review identified several areas where costs can be reduced. These are:

- removal of some controls, at least in some jurisdictions (e.g. requirement to hold a licence to supply clinical samples);
- less restrictive controls (e.g. storage requirements for *Schedule 2* medicines); and
- coregulation (e.g. a code of practice for supply of clinical samples).

With the objective of the controls centred on the need to address the information asymmetry, the Review also identified possibilities for improvement in ways to provide knowledge to the public and overcome the lack of skills of most consumers in the choice and use of medicines and poisons. Of particular interest to the Review in this regard was the effectiveness of labels, the availability of the Consumer Medicine Information leaflets, the use of advertising as information and education, and the availability and quality of counselling by doctors and pharmacists.

In addition, the Review believed it appropriate to make recommendations to improve the administrative efficiency of the legislation, particularly where this involves operation of the Schedule Committee, the National Coordinating Committee for Therapeutic Goods, inter-agency liaison, inter-government consistency and duplication of the safety assessments required for scheduling.

Conclusions

Based on its analysis, the Review determined that:

- there are sound reasons for Australia to have a comprehensive system of legislative controls that regulates drugs, poisons and controlled substances – notwithstanding the fact that many of these controls restrict competition;
- the level of regulation should be reduced in some areas and, in other areas, a coregulatory approach is appropriate;
- the efficiency of the regulatory system of controls and their administration across a significant number of areas should be improved by:

  - developing a uniform approach across jurisdictions to the legislation that regulates access to and use of drugs, poisons and controlled substances;
  - ensuring the interface between the various pieces of legislation is rational and avoids duplication and overlap, in order to achieve legislative alignment between specific drugs, poisons and controlled substances legislation and related legislation; and
  - ensuring the administrative processes associated with the legislation are efficient and do not impose any unnecessary costs on industry, government or consumers; and
- non-legislative measures should be used to complement legislative measures in meeting the underlying objectives of drugs, poisons and controlled substances legislation.

In brief, the Review recommends that:

- uniformity be improved by transferring the controls for advertising and product labels and packaging for medicines and agvet chemicals to Commonwealth legislation where;
  - the prohibition on advertising prescription medicines is retained, except that publication of the Consumer Medicine Information should be permitted as should advertisements which only provide information about the price of medicines or general information about disease states, in accordance with a code of practice underpinned by legislation to promote the informational nature of these advertisements; and
  - controls over labelling are amended to make them more outcomes focused;
- provisions relating to licences for *Schedule 5* and *6* substances be repealed in those jurisdictions that still have these provisions,
- mandatory requirements for recording the supply of *Schedule 3* substances be repealed in those jurisdictions that have such provisions;
- uniformity be improved by the development of model legislation that includes provisions for all matters related to the supply of medicines for therapeutic purposes and domestic supply of agricultural and veterinary and household chemicals, and incorporating:
  - clinical samples as a condition of licence for companies and a requirement that company representatives be permitted to supply the samples, provided they also comply with the code; and
  - consumer samples of *Schedule 5* and *6* poisons;
- licence requirements be outcomes focused and that, where appropriate, these be consistent with the requirements under Commonwealth legislation for the import, export and manufacture of controlled substances;
- the National Coordinating Committee on Therapeutic Goods be responsible for developing and maintaining this model legislation; and
- efficiency of the scheduling system be improved by:

- more closely linking the evaluation process for medicines and agvet products with the scheduling process; and
- establishing separate committees to make decisions about the scheduling of medicine and poisons.

RECOMMENDATIONS

Recommendation 1: Objectives of legislative framework

That all Commonwealth, State and Territory governments agree that:

a) There are net benefits to the Australian community as a whole in having a comprehensive legislative framework that regulates drugs, poisons and controlled substances, the principal objectives of the legislation being to promote and protect public health and safety by preventing:
   - accidental poisoning;
   - deliberate poisoning;
   - medicinal misadventures; and
   - diversion for abuse or manufacture of substances of abuse.

b) All relevant Commonwealth and State and Territory legislation needs explicitly to incorporate these objectives and be effective, transparent, equitable and the controls the minimum necessary to achieve these objectives.

Recommendation 2: On-going evaluation of the controls

Commonwealth, State and Territory governments allocate public health funding to ongoing research, including data collection to evaluate and monitor the effectiveness of the legislative controls in achieving the objectives of drugs, poisons and controlled substances legislation with a view to continually improving the cost effectiveness of those regulatory controls.

Recommendation 3: Objectives of scheduled medicine controls

That all Commonwealth, State and Territory governments agree that legislation covering the supply of scheduled medicines should explicitly set out its objectives. These objectives are to ensure that:

- in the case of prescription medicines, the conditions from which consumers are suffering are diagnosed correctly and the most appropriate treatment prescribed;
- the consumers of prescription medicines have adequate information and understanding necessary to enable them to use medicines safely and effectively;
- in the case of over-the-counter medicines, consumers have adequate information and understanding to enable them to select the most appropriate medicines for their condition and to use them safely and effectively, taking into account their health status; and

- the *Agricultural and Chemical Code Act 1994* to include all controls on advertising, labelling (except signal headings) and packaging for agvet products, provided this is consistent with the requirements for packaging of household chemicals included in the *Standard for the Uniform Scheduling of Medicines and Poisons*.

Recommendation 23: Complementary therapeutic goods legislation

That all Commonwealth, State and Territory jurisdictions agree that all States and Territories adopt the *Therapeutic Goods Act 1989* by reference into the relevant legislation.

Recommendation 24: Uniform national model legislation

That all Commonwealth, State and Territory governments agree that:

a) The Australian Health Ministers Advisory Committee expand the Terms of Reference of the National Coordinating Committee on Therapeutic Goods to give it responsibility for developing advice for the Australian Health Ministers Conference through the Australian Health Ministers' Advisory Committee on developing and maintaining model medicines and poisons legislation. The Terms of Reference should include responsibility for undertaking any necessary consultation to enable regulatory impact statements to be prepared and establishing supporting mechanisms which put in place an effective and efficient national system of controls.

b) The National Coordinating Committee on Therapeutic Goods develop model legislation that includes provisions for all matters relating to the supply of medicines for therapeutic purposes and to domestic supply of household chemicals:

   - setting out the objectives of the legislation;
   - specifying agreed outcomes for controls; and
   - identifying the specific levels of controls in the areas of:
     - licensing;
     - dispensing labels;
     - household chemical packaging;
     - storage and handling of drugs;
     - recording and reporting; and
     - supply of clinical samples.

c) State and Territory governments adopt the model legislation by reference.

Recommendation 25: Repeal of State and Territory legislation

That State and Territory governments repeal existing legislation relating to controls on labelling, packaging, advertising, access restrictions, licences, recording, reporting, storage, handling and supply of clinical samples of medicines.

Attachment 3

AUSTRALIAN HEALTH MINISTERS' ADVISORY COUNCIL
Working Party

response to

the Review of Drugs, Poisons and Controlled Substances

Legislation (the Galbally Review)

April 2003

RECOMMENDATION 23

Complementary therapeutic goods legislation

That all Commonwealth, State and Territory jurisdictions agree that all States and Territories adopt the Therapeutic Goods Act 1989 by reference into the relevant legislation.

Summary

The Review has recommended that, in the interests of uniformity, all states adopt the Commonwealth Therapeutic Goods Act by reference.

Comments and Discussion

All States and Territories agree but in cases where complementary legislation has not been introduced there may be a delay in preparation of legislation and implementation of changes by States and Territories.

So far only NSW, Tasmania and Victoria have complementary legislation. NSW and Tasmania, which adopt the Therapeutic Goods Act by reference, would not need to make any amendments. As Victoria has mirror legislation (its own provisions), and does not simply adopt by reference the Therapeutic Goods Act as in force from time to time, it must prepare amendments each time the Commonwealth Act is amended. ACT has drafted its legislation but it has low parliamentary business priority. The Northern Territory and Queensland are in the drafting phase. The remaining States support the concept of complementary legislation but are not yet at the stage of drafting.

As well as putting in place complementary legislation, legislative action is needed to ensure that all the provisions can be enforced. If the Commonwealth is to enforce the provisions of State or Territory laws, all jurisdictions may need to enact provisions to deal with a recent High Court case, *Hughes.* This case casts doubt about Commonwealth officers' ability to exercise powers under certain State and Territory laws. The TGA has begun the legislative process to amend the Therapeutic Goods Act to make it clear that Commonwealth officers may take action under State or Territory provisions, but do not have a duty to do so. To demonstrate that no duty exists it must be clear that other persons can take the action. If State or Territory laws do not give enforcement powers to State officials, it is most likely that those laws will require amending to insert provisions permitting those officials to exercise the powers and perform the functions under the State legislation.

The PIMC submission notes that the this recommendation may be relevant to the agvet scheme, dependent on whether the Therapeutic Goods Act is amended to include advertising controls on Schedule 4 medicines for veterinary use.

NCP Implications

Yes, for some States and Territories.

Recommendation to COAG

That recommendation 23 of the Review be accepted.

Action to Implement

Some States may need to make legislative changes.

Extract from the Commonwealth Therapeutic Goods Act 1989 (25/10/2013)

4 Objects of Act

(1) The objects of this Act are to do the following, so far as the Constitution permits:

(a) provide for the establishment and maintenance of a national system of controls relating to the quality, safety, efficacy and timely availability of therapeutic goods that are:

(i) used in Australia, whether produced in Australia or elsewhere; or

(ii) exported from Australia;

(b) to provide a framework for the States and Territories to adopt a uniform approach to control the availability and accessibility, and ensure the safe handling, of poisons in Australia.

(1A) The reference in paragraph (1)(a) to the efficacy of therapeutic goods is a reference, if the goods are medical devices, to the performance of the devices as the manufacturer intended.

(2) This Act is therefore not intended to apply to the exclusion of a law of a State, of the Australian Capital Territory or of the Northern Territory to the extent that the law is capable of operating concurrently with this Act.

6 Operation of Act

(1) This Act applies to:

(a) things done by corporations; and

(b) things done by natural persons or corporations in so far as those things are done:

(i) in the course of, or in preparation for, trade or commerce between Australia and a place outside Australia, among the States, between a State and a Territory or between 2 Territories; or

(ii) under a law of the Commonwealth relating to the provision of pharmaceutical or repatriation benefits; or

(iii) in relation to the Commonwealth or in relation to an authority of the Commonwealth.

(2) Without limiting the effect of this Act apart from this subsection, this Act also has the effect it would have if the reference in paragraph (1)(a) to things done by corporations were confined to things done by trading corporations for the purposes of their trading activities.

Interactions between Clth TGA and State Law

6AAA Commonwealth consent to conferral of functions etc. on its officers and authorities by corresponding State laws

(1) A corresponding State law may confer functions or powers, or impose duties, on:
(a) a Commonwealth officer; or
(b) a Commonwealth authority.

(2) Subsection (1) does not authorise the conferral of a function or power, or the imposition of a duty, by a corresponding State law to the extent to which:
(a) the conferral or imposition, or the authorisation, would contravene any constitutional doctrines restricting the duties that may be imposed on Commonwealth officers or Commonwealth authorities; or
(b) the authorisation would otherwise exceed the legislative power of the Commonwealth.

(3) Subsection (1) does not extend to a function, power or duty of a kind specified in regulations made for the purposes of this subsection.

(4) This Act is not intended to exclude or limit the operation of a corresponding State law that confers any functions or powers, or imposes any duties, on a Commonwealth officer or Commonwealth authority to the extent to which that law:
(a) is consistent with subsections (1) to (3); and
(b) is capable of operating concurrently with this Act.

6AAB When duty imposed

Application

(1) This section applies if a corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority.

State legislative power sufficient to support duty

(2) The duty is taken not to be imposed by this Act (or any other law of the Commonwealth) to the extent to which:
(a) imposing the duty is within the legislative powers of the State concerned; and
(b) imposing the duty by the corresponding State law is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

Note: If this subsection applies, the duty will be taken to be imposed by force of the corresponding State law (the Commonwealth having consented under section 6AAA to the imposition of the duty by the corresponding State law).

Commonwealth legislative power sufficient to support duty but State legislative powers are not

(3) If, to ensure the validity of the purported imposition of the duty, it is necessary that the duty be imposed by a law of the Commonwealth (rather than by force of the corresponding State law), the duty is taken to be imposed by this Act to the extent necessary to ensure that validity.

(4) If, because of subsection (3), this Act is taken to impose the duty, it is the intention of the Parliament to rely on all powers available to it under the Constitution to support the imposition of the duty by this Act.

(5) The duty is taken to be imposed by this Act in accordance with subsection (3) only to the extent to which imposing the duty:
  (a) is within the legislative powers of the Commonwealth; and
  (b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

(6) To avoid doubt, neither this Act (nor any other law of the Commonwealth) imposes a duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing such a duty would:
  (a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or
  (b) otherwise exceed the legislative power of the Commonwealth.

(7) Subsections (1) to (6) do not limit section 6AAA.

6AAC Imposing duty under State law

(1) This section:
  (a) applies only for the purposes of the application of the provisions of this Act or another law of the Commonwealth (with or without modification) as a law of a State by a provision of a corresponding State law; and
  (b) does not apply for those purposes if the corresponding State law otherwise provides.

(2) If the corresponding State law purports to impose a duty on a Commonwealth officer or Commonwealth authority to do a particular thing, the duty is taken to be imposed by the corresponding State law to the extent to which imposing the duty:
  (a) is within the legislative powers of the State; and
  (b) is consistent with the constitutional doctrines restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority.

(3) To avoid doubt, the corresponding State law does not impose the duty on the Commonwealth officer or Commonwealth authority to the extent to which imposing the duty would:
  (a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or
  (b) otherwise exceed the legislative powers of the State.

(4) If imposing on the Commonwealth officer or Commonwealth authority the duty to do that thing would:
(a) contravene any constitutional doctrine restricting the duties that may be imposed on a Commonwealth officer or Commonwealth authority; or
(b) otherwise exceed the legislative powers of both the State and the Commonwealth; the corresponding State law is taken instead to confer on the officer or authority a power to do that thing at the discretion of the officer or authority.

6AAD Conferral of jurisdiction on federal courts

If:
(a) a provision of a corresponding State law purports to apply a provision of a law of the Commonwealth (the ***applied provision***) as a law of the State; and
(b) the applied provision purports to confer jurisdiction in relation to a matter on a federal court; the jurisdiction in relation to that matter is taken to be conferred on the court by this section.

6AAE Consequences of State law conferring duty, function or power on Commonwealth officer or Commonwealth authority

(1) If a corresponding State law confers on a Commonwealth officer or Commonwealth authority:
(a) the function of including goods in the Register; or
(b) the power to include goods in the Register; the officer or authority may include the goods in the Register in accordance with the corresponding State law.

(2) If a corresponding State law authorises or requires a Commonwealth officer or Commonwealth authority to cancel the inclusion of goods in the Register, the officer or authority may cancel the inclusion of the goods in the Register in accordance with the corresponding State law.

(3) The inclusion of goods in the Register under subsection (1) does not subject any person to any liability whatever under this Act, except a liability under Part 6-1.

(4) A Commonwealth officer or Commonwealth authority may make any notations in the Register that the officer or authority considers necessary to identify entries that relate to goods included in the Register under subsection (1).

(5) Goods may be included in the Register under subsection (1) even though the same goods have already been included in the Register under another provision of this Act.

(6) A reference in this section to the inclusion of goods in the Register is a reference to the inclusion of the goods:
(a) in the part of the Register for goods known as registered goods; or
(b) in the part of the Register for goods known as listed goods; or
(ba) in the part of the Register for biologicals included under Part 3-2A; or
(c) in the part of the Register for medical devices included under Chapter 4.

6B Review of certain decisions under State laws

(1) Application may be made to the Administrative Appeals Tribunal for review of a reviewable State decision.

(2) A decision made by the Secretary in the performance of a function, or the exercise of a power, conferred by a corresponding State law is a reviewable State decision for the purpose of this section if:
  (a) the law under which the decision was made provides for review by the Administrative Appeals Tribunal; and
  (b) the decision is declared by the regulations to be a reviewable decision for the purposes of this section.

(3) For the purposes of subsection (1), the *Administrative Appeals Tribunal Act 1975* has effect as if a corresponding State law were an enactment.

6C Fees payable to Commonwealth under State laws

(1) This section applies to fees payable to the Commonwealth under a State law in respect of the performance or exercise of functions or powers conferred by that law on the Secretary.

(2) The Secretary may make arrangements with the appropriate authority of a State, of the Australian Capital Territory or of the Northern Territory in relation to the payment to the Commonwealth of fees to which this section applies.

7 Declaration that goods are/are not therapeutic goods

(1) Where the Secretary is satisfied that particular goods or classes of goods:
  (a) are or are not therapeutic goods; or
  (b) when used, advertised, or presented for supply in a particular way, are or are not therapeutic goods; the Secretary may, by order published in the *Gazette*, declare that the goods, or the goods when used, advertised, or presented for supply in that way, are or are not, for the purposes of this Act, therapeutic goods.

(1A) In deciding whether particular goods or classes of goods:
  (a) are therapeutic goods; or
  (b) when used, advertised, or presented for supply in a particular way, are therapeutic goods; the Secretary must disregard paragraphs (e) and (f) of the definition of ***therapeutic goods*** in subsection 3(1).

(2) The Secretary may exercise his or her powers under this section of his or her own motion or following an application made in writing to the Secretary.

(3) A declaration under this section takes effect on the day on which the declaration is published in the *Gazette* or on such later day as is specified in the order.

(4) If a declaration under this section:
  (a) is a declaration that particular goods or classes of goods are not therapeutic goods; and
  (b) applies wholly or partly to goods that, apart from this section, would be medical devices; the goods are not medical devices, or are not medical devices when used, advertised, or presented for supply in the way specified in the declaration.

7A Authorised persons

The Secretary may, in writing, authorise any of the following persons to exercise powers under a specified provision of this Act:

(a) an officer of the Department, of another Department or of an authority of the Commonwealth;

(b) an officer of:

(i) a Department of State of a State; or

(ii) a Department or administrative unit of the Public Service of a Territory; or

(iii) an authority of a State or of a Territory; being a Department, unit or authority that has functions relating to health matters or law enforcement matters.

Author's Note: Sections 7B, C and D not included

8 Power to obtain information with respect to therapeutic goods

(1) The Secretary may, by notice in writing given to a person who has imported into Australia or has supplied in Australia:

(a) therapeutic goods; or

(b) goods in relation to which the Secretary is considering making a declaration under section 7; request the person to give to an officer of the Department identified in the notice, within such reasonable period as is specified in the notice, information required by the notice concerning the composition, indications, directions for use or labelling of the goods or concerning advertising material relating to the goods.

(1A) A notice under subsection (1) may require the information to be given:

(a) in writing; or

(b) in accordance with specified software requirements:

(i) on a specified kind of data processing device; or

(ii) by way of a specified kind of electronic transmission.

(2) A person must not fail to comply with a notice given to the person under this section.

Penalty: 60 penalty units.

(3) Subsection (2) does not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (3). See subsection 13.3(3) of the *Criminal Code*.

(4) An offence under subsection (2) is an offence of strict liability.

9 Arrangements with States etc.

(1) The Minister may make arrangements with the appropriate Minister of a State, of the Australian Capital Territory or of the Northern Territory for the carrying out by that State or Territory, on behalf of the Commonwealth, of:

(a) the evaluation of therapeutic goods for registration; or

(aa) the evaluation of a biological, other than a Class 1 biological, for inclusion in the Register under Part 3-2A; or

(b) the inspection of manufacturers of therapeutic goods; or

(c) other functions under this Act or the regulations.

(2) An arrangement under this section may provide for the payment to a State or Territory of amounts in respect of the performance of functions under the arrangement.

Powers of Authorised Persons

From the Commonwealth Therapeutic Goods Act 1989 (25/10/2013)

48 General powers of authorised persons in relation to premises

(1) The powers an authorised person may exercise under paragraphs (1)(b) and 47(1)(b) are as follows:
- (a) to search the premises and any thing on the premises;
- (b) to inspect, examine, take measurements of, conduct tests on or take samples of any therapeutic goods on the premises or any thing on the premises that relates to any therapeutic goods;
- (c) to make any still or moving image or any recording of the premises or any thing on the premises;
- (d) if the authorised person was only authorised to enter the premises because the occupier of the premises consented to the entry—to require the occupier to:
  - (i) answer any questions put by the authorised person; and
  - (ii) produce any book, record or document requested by the authorised person;
- (e) if the authorised person was authorised to enter the premises by a warrant under section 49 or 50—to require any person in or on the premises to:
  - (i) answer any questions put by the authorised person; and
  - (ii) produce any book, record or document requested by the authorised person;
- (f) to inspect any book, record or document on the premises;
- (g) to take extracts from or make copies of any such book, record or document;
- (h) to take onto the premises such equipment and materials as the authorised person requires for the purpose of exercising powers in relation to the premises.

Author's Note: Sub section 48(2) appears to be deleted

(3) A person must not refuse or fail to comply with a requirement under paragraph (1)(e).

Penalty: 30 penalty units.

(3A) Subsection (3) does not apply if the person has a reasonable excuse.

Note: The defendant bears an evidential burden in relation to the matter in subsection (3A). See subsection 13.3(3) of the Criminal Code.

(4) It is a reasonable excuse for a person to refuse or fail to answer a question or produce a document if answering the question, or producing the document, would tend to incriminate the person.